REMARKS

Please charge the fee for these claim amendments to deposit account number 50-1273. If any additional fee should become due or credit become payable during the pendency of these proceedings, the Examiner is authorized to charge or credit the same to deposit account number 50-1273.

In accordance with 37 C.F.R. §1.121, a marked up copy of the presently amended specification paragraphs and claims is appended hereto. Additions are noted by underlining. Deletions are noted by bracketing. Furthermore, to ensure that Applicants' pending claims match those of the Patent Office, a clean copy of the entire set of pending claims is also appended hereto.

The amendments to the specification are merely to correct typographical inconsistencies and dates of documents discussed therein. These amendments are fully supported by the originally filed specification.

Support for amended claims 1 and 2 can be found, for example, in originally filed claims 1 and 2 and on page 10, lines 4-18, page 29, lines 14-17, and Examples 1-4 of the specification.

The amendments to claims 4 and 8 are merely to add further multiple-dependencies into the respective claims. These amendments are not necessitated for patentability of the claims and do not narrow the respective claim's scope.

Support for amendments to claim 14 and 19 can be found, for example, in Example 8 and on page 19, line 28, to page 20, line 8, of the specification.

Support for new claims 25 and 26 can be found throughout the originally filed specification, including the claims, page 19, line 28, to page 20, line 8, and Example 8.

Support for new claims 27 and 28 can be found, for example, in originally filed claims 3 and 4 and on page 11, lines 25-31, page 29, lines 14-17, and Examples 1-4 of the specification.

Support for new claim 29 can be found, for example, on page 19, line 28, to page 20, line 8, and Example 8 of the specification.

Support for new claims 30 and 31 can be found, for example, in originally filed claims 1 and 2 of the specification.

Allowable Subject Matter

In the Office Action, the Examiner states: "[T]he closest prior art of record (the Guidobono references, especially the PEPTIDES 1994 reference) teach[es] away from the peripheral administration

of amylin compounds (as well as calcitonin and CGRP compounds) for treating/preventing gastritis/gastric ulcer (e..g induced by ethanol or NSAID's)." The Examiner also set forth two independent claims, indicating that the two independent claims are allowable over the prior art of record. Applicants appreciate the Examiner's suggestions in this regard. New claims 25, 26, and 29 have been added in response to the Examiner's suggestions. Allowance of these newly added claims is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Rejections

The First Rejection

Claims 14 and 19 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner contends that claims 14 and 19, prior to the broadening amendments presented herewith, contain new matter in that they are "broadly drawn to a large genus of 'amylin or amylin agonist' which possesses an [IC_{50}] of 'about [50 pM] (or [30 pM]) or less." The Examiner further contends that "to the extent that the claim reads on determining [IC_{50}] values in assays other than described and to the extent that the claim extends to amlin [sic] analogs other than those specifically described in Table 1, this added breadth constitutes new matter." This rejection is traversed.

Claims 14 and 19, respectively, now recite that the IC_{50} of the recited amylin or amylin agonist is either "about 5 nM or less" or "about 1 nM or less." On page 19, line 28 to page 20, line 6, of the present specification, Applicants teach:

> The activity of amylin agonists may be evaluated using certain biological assays described herein. The receptor binding assay can identify both candidate amylin agonist and antagonists and can be used to evaluate binding .... Preferably agonist compounds exhibit activity in the receptor binding assay on the order of less than about 1 to 5 nM, preferably less than about 1 nM and more preferably less than about 50 pM. (emphasis added)

Clearly, in light of this teaching, for example, one of ordinary skill in the art would not refute that the inventors, at the time the application was filed, had possession of the invention set forth in claims 14 and 19, irrespective of the amendments presented herewith.

The teachings of Applicants' specification, with respect to methods for the evaluation of the activity of a compound, are broader than the specific evaluation method used to generate the values

recited in Table 1. One of ordinary skill in the art would readily appreciate that there are a variety of assays useful for determining the activity of compounds, such as those of the present invention. Data generated using any suitable assay can be readily correlated with data generated in the exemplified rat receptor binding assay.

Furthermore, one of ordinary skill in the art would readily appreciate that any suitable amylin or amylin agonist, including analogues thereof, can be used according to the present invention. Again, the specific compounds evaluated in Table 1 are only a few of the compounds encompassed within the broader teachings of the specification.

In order to expedite prosecution, however, the claims 14 and 19 have now been amended to recite that the recited IC_{50} values are in "rat receptor binding assays." This language is similar to that suggested by the Examiner in claims set forth with the indication of Allowable Subject Matter. In light of Applicants' teachings and with the present amendment to claims 14 and 19, this rejection should be withdrawn.

The Second Rejection

Claims 17 and 18 stand rejected under 35 U.S.C. §112, first paragraph. Although traversed, this rejection is now moot due to the cancellation of claims 17-18. Thus, withdrawal of this rejection is requested.

The 35 U.S.C. §112, Second Paragraph, Rejections

The First Rejection

Claims 1-2, 4-10, 13-16, and 19-24 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Examiner inquires as to the metes and bounds of "CGRP" recited in claim 1. In making this inquiry, the Examiner asks whether CGRP analogues are included within the term "CGRP" recited in claim 1.

Applicants intend that the proviso recited in claim 1, wherein CGRP is mentioned, is intended to exclude only CGRP and not its analogues. This is consistent with the wording of the claim and the rest of the specification. In light of this clarification, withdrawal of this rejection is respectfully requested.

The Second Rejection

Claims 14 and 18-19 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Examiner contends that these claims are incomplete for "omitting essential steps, such omission amounting to a gap between the steps." This rejection is traversed. Furthermore, due to its cancellation, this rejection is now moot with respect to claim 18.

Applicants respectfully disagree with the Examiner's assertion that claims 14 and 18-19, prior to presently being amended or cancelled, omitted essential steps, necessitating a rejection under 35 U.S.C. §112, second paragraph. While the specification exemplifies calculation of IC_{50} values in a rat receptor binding assay, the specification also makes clear that rat receptor binding assays are only one example of an assay in which activity of the compounds of the invention may be evaluated. (See, for example, page 20, lines 2-8, of the specification) Nevertheless, in order to expedite prosecution, claims 14 and 19 now recite that the claimed IC_{50} value is in a rat receptor binding assay.

Applicants also wish to point out that they are not claiming an assay method. What applicants are claiming, however, is the use of an amylin or an amylin agonist having the particularly claimed IC_{50} value in the recited assay for use in methods according to the present invention. One of ordinary skill in the art would recognize how to calculate the IC_{50} value of an amylin or an amylin agonist in any given assay. If an IC_{50} value is calculated in an assay other than that recited in the claims, one of ordinary skill in the art is readily able to correlate that IC_{50} value with the IC_{50} value obtained using the particular rat receptor binding assay described in the present specification. For at least the foregoing reasons, withdrawal of this rejection is respectfully requested.

In any event, the Examiner indicated that amending the rejected claims to "recite the use of a rat receptor binding assay while pointing to the specification example relating thereto will overcome this rejection." To expedite prosecution, and as discussed above with respect to the 35 U.S.C. §112, first paragraph, rejections, claims 14 and 19 have been amended to recite that the claimed IC_{50} values are in a rat receptor binding assay. Again, withdrawal of this rejection is requested.

<u>The 35 U.S.C. §102(b)/§103(a) Rejections</u>

The First Rejection

Claims 1-2, 5-8, 13, 15-16, and 20-24 stand rejected under 35 U.S.C. §102(b)/§103(a) as allegedly being anticipated by, or obvious over, Kolterman et al. (PCT Publication No. WO 95/07098). In making this rejection, the Examiner essentially expanded the previous rejection over Kolterman et al. to encompass claims added with Applicants' last Response. This rejection is traversed.

The Examiner continues to argue that Kolterman et al.'s teachings are within the scope of the presently claimed invention. The Examiner refers to the claim language drawn to the prevention of gastritis and gastric ulcerations. As stated in the Office Action, the Examiner contends: "The actual (e.g. peripheral) administration to humans of compounds (e.g, AC-O137) in dosages within the scope of the presently claimed invention would necessarily anticipate the presently claimed invention drawn to the prevention of gastritis/ulcers." (emphasis omitted) Applicants respectfully disagree.

Kolterman et al. is directed toward regulating gastrointestinal motility in a subject (e.g., by reducing or delaying gastric emptying) by administering an amylin or an amylin agonist. Among many other uses for the methods described therein, Kolterman et al. teach that the methods are "useful in the treatment of, for example, post-prandial hyperglycemia, a complication associated with type 2 (non-insulin dependent) diabetes mellitus." (See, for example, page 21, 2nd full paragraph, of Kolterman et al.) Other uses described therein include those related to subjects "undergoing gastrointestinal diagnostic procedure, for example radiological examination or magnetic resonance imaging . . . [or] suffering from a gastro-intestinal disorder, for example, spasm (which may be associated with acute diverticulitis, a disorder of the biliary tract or a disorder of the Sphincter of Oddi)." (See, for example, page 23, 1st full paragraph, of Kolterman et al.) Treatment of "post-prandial dumping syndrome" is also described. (See, for example, page 23, 2nd full paragraph, of Kolterman et al.) Still another use described therein is for "treating gastric hypomotility [that] is a consequence of diabetic neuropathy . . . or anorexia nervosa." (See, for example, pages 23-24, bridging paragraph, of Kolterman et al.) Still another use described therein is for "treating ingestion of a toxin . . . to prevent or reduce passage of stomach contents to the intestines and aspirating the stomach contents." (See, for example, page 24, 2nd full paragraph, of Kolterman et al.)

Notably missing from the teachings of Kolterman et al. is a teaching or suggestion that an amylin or an amylin agonist can be used for treating or preventing gastritis or gastric ulceration in a subject in need thereof. Claims 1 and 2 have been amended to clarify this distinction between the claimed invention and the teachings of Kolterman et al.

The Examiner indicated that a limitation to "at risk" subjects would not be sufficient to overcome the present rejection unless it was also demonstrated that Kolterman et al.'s subjects, "which include subjects undergoing gastrointestinal procedures and who have gastrointestinal disorders," would not be within the group of "at risk" subjects. Applicants submit that the subjects of Kolterman et al. are not inherently those subjects in need of treatment or prevention of gastritis or gastric ulceration. Therefore, Kolterman et al. does not teach each and every limitation of the claimed invention.

As outlined above, the Kolterman et al. subjects include those with: post-prandial hyperglycemia, a complication associated with type 2 diabetes mellitus; post-prandial dumping syndrome; gastric hypomotility, which is a consequence of diabetic neuropathy or anorexia nervosa; or toxin ingestion, as well as those undergoing a gastrointestinal diagnostic procedure or suffering a gastrointestinal disorder, such as spasm (e.g., spasm associated with acute diverticulitis, biliary tract disorders, or Sphincter of Oddi disorders). In supporting the rejection, the Examiner refers to the latter group of patients, those undergoing gastrointestinal diagnositic procedures or suffering a gastrointestinal disorder. One of ordinary skill in the art would understand that those subjects are benefiting from Kolterman's method by, for example, its ability to slow gastric emptying of a radio-opaque agent used for the purposes of diagnosis.

In contrast, subjects according to claims 1 and 2 of the present invention, who are in need of treatment or prevention of gastritis or gastric ulceration, are not generally in need of slowing or regulation of gastric motility. In fact, one of ordinary skill in the art would likely predict that slowing of gastric emptying would be contraindicated in patients who are at risk for developing gastritis or gastric ulceration, for example, because of their ingestion of ethanol or non-steroidal anti-inflammatory drugs (NSAIDS). As one can imagine, slowing of gastric emptying in such subjects, would be expected to leave the irritating substance (e.g., ethanol or NSAIDS) in contact with the gastric mucosa for a longer period of time, leading to additional irritation.

One of ordinary skill in the art is readily able to identify patients at risk for gastritis or gastric ulceration (i.e., those subjects in need of treatment or prevention for gastritis or gastric ulceration), since many factors are known to put patients at risk for such conditions. For example, acute gastritis occurs in a large percentage of critically ill hospital patients, burn victims, individuals taking certain medications or dosages (e.g., as high doses of corticosteroids, antibiotics, NSAIDS, etc.), and other individuals who have sustained major trauma or who have undergone surgical procedures, brain injury, etc. Kolterman

et al. does not address this needy patient population, one which is able to benefit from the present invention. In view of the absence of teaching or suggestions in Kolterman et al. of treating or preventing gastritis or gastric ulceration in a subject in need thereof, claims 1 and 2 are deemed allowable over Kolterman et al.

Claims 5-8, 13, 15-16 and 20-24 ultimately depend from one of claims 1 or 2. Thus, withdrawal of this rejection in its entirety is requested.

The Second Rejection

Claims 14, 18, and 19 stand rejected under 35 U.S.C. §102(b)/§103(a) as allegedly being anticipated by, or obvious over, Kolterman et al. (PCT Publication No. WO 95/07098) alone, or further in view of the specification to demonstrate inherency. This rejection is traversed. Furthermore, due to its cancellation, the rejection with respect to claim 18 is now moot.

In making this rejection, the Examiner refers to Section 2131.01(d) of the Manual of Patent Examining Procedure (MPEP). Applicants do not find a Section 2131.01(d) in the MPEP. Applicants respectfully request clarification as to which section of the MPEP is relied on by the Examiner.

In any event, claims 14 and 19 ultimately depend from one of claims 1 or 2, which have now been amended. Thus, for the reasons given with respect to the First Rejection under 35 U.S.C. §102(b)/§103(a), this rejection, as applied to claims 14 and 19, is now moot. Withdrawal of this rejection is requested.

The Third Rejection

Claims 1, 2, 5, 6, 13, 14, and 20-24 stand rejected under 35 U.S.C. §102(b)/§103(a) as allegedly being anticipated by, or obvious over, Wu et al. (AN – 1995-351860; XP – 002163755). This rejection is traversed.

The Examiner acknowledges that the cited document is "silent as to how the chinese medicine [described therein] is administered . . . ." However, the Examiner asserts that "one would immediately envisage (e.g. anticipate) the administration of the chinese medicine peripherally (e.g. oral) since 'medicines' are rarely given to humans through the brain or spinal cord (e.g. centrally) and further in view of the limited number of art-established means of administering medicinal compositions." In the

alternative, the Examiner asserts that "peripheral' administration of the 'amylin' containing chinese medicine would be prima facie obvious."

The Examiner further alleges that the "IC_{50} values within the scope of the presently claimed invention for 'amylin' represent an 'inherent' property of amylin." The Examiner considers that distinguishing the "amylin" of Wu et al. from the "amylin" described in the specification would overcome this rejection.

The Examiner's application of Wu et al. to the present claims is similar to the application of Liu et al. (WPIDS Abstract No. 98-019088) in the Office Action dated July 12, 2000. For the same reasons that withdrawal of that rejection was requested, and so made by the Patent Office, Applicants respectfully request that this rejection be withdrawn.

Plainly, the "amylin" referred to in Wu et al. is not the same as the pancreatic hormone amylin, which is peptidic. In the New English-Chinese Medical Dictionary, of which a copy of the relevant pages is attached hereto as Exhibit A, the word "amylin" translates essentially to an "insoluble starch and fiber." Consistent with this definition, the term "amylin" as used in the Wu et al. abstract is manifestly relegated to a subsidiary role in the admixture. The active ingredients are listed first, while subsidiary "fillers" follow. The term "amylin" appears with the filler, sugar, and not with the active primary medicinal components listed earlier. Plainly, the "amylin" of Wu et al. is not the pancreatic hormone known as amylin, which would not be regarded by one of ordinary skill in the art as merely a filler. Again, withdrawal of this rejection is requested.

The Fourth Rejection

Claims 17 and 18 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Guidobono et al. (British Journal of Pharmacology, Vol. 120(4), pp. 581-86, February 1997). This rejection is traversed. However, due to the cancellation of claims 17-18, this rejection is now moot. Thus, this rejection should be withdrawn.

The Fifth Rejection

Claims 1, 2, 6, 13, 14, 17, 18, and 23 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Guidobono et al. (Peptides, Vol. 15(4), pp. 699-702, 1994). This rejection is traversed. Furthermore, due to its cancellation, this rejection is now moot with respect to claims 17-18.

The Examiner refers to the claim language drawn to the prevention of gastritis and gastric ulcerations in supporting this rejection. Guidobono et al. does not teach or suggest the use of amylin or amylin agonists in treating or preventing gastritis or gastric ulceration in a subject in need thereof. Applicants have amended claims 1 and 2 to indicate that the method of treating or preventing gastritis or gastric ulceration is for use on a subject in need thereof. Clearly, Guidobono et al., who discuss administration of amylin to experimental rats, which are sacrificed within a few hours after being administered amylin, do not teach or suggest this aspect of the present invention, as recited in claims 1 and 2. Claims 6, 13, 14 and 23 ultimately depend from one of claims 1 or 2. Thus, withdrawal of this rejection is requested, as this amendment makes the Examiner's arguments in support of the rejection moot.

Conclusion

In conclusion, Applicants respectfully submit that all pending claims are in condition for allowance. The Examiner is invited to contact Applicants' undersigned Representative if it is believed that prosecution may be furthered thereby.

Respectfully Submitted,

Young et al.

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MARKED UP VERSION OF AMENDED SPECIFICATION

Replace the paragraph on page 5, lines 19-30 with the following:

--In fat cells, contrary to its action in muscle, amylin has no detectable actions on insulin-stimulated glucose uptake, incorporation of glucose into triglyceride, CO_2 production (Cooper et al., *Proc. Natl. Acad. Sci.*, 85:7763-7766 (1988)), epinephrine-stimulated lipolysis, or insulin-inhibition of lipolysis (Lupien and Young, "Diabetes Nutrition and Metabolism – Clinical and Experimental," Vol. 6(1), pages [1318] 13-18 (February 1993)). Amylin thus exerts tissue-specific effects, with direct action on skeletal muscle, and indirect (via supply of substrate) effects on liver, while adipocytes appear "blind" to the presence or absence of amylin.--

Replace the paragraphs on page 6, line 1, through page 7, line 13, with the following:

--It has also been reported that amylin can have marked effects on secretion of insulin. In isolated islets (Ohsawa et al., *Biochem. Biophys. Res. Commun.*, 160(2):961-967 (1989)), in the perfused pancreas (Silvestre et al., *Reg. Pept.*, 31:23-31 [(1991)] (1990)), and in the intact rat (Young et al., *Mol. Cell. Endocrinol.*, 84:R1-R5 (1992)), some experiments indicate that amylin inhibits insulin secretion. Other workers, however, have been unable to detect effects of amylin on isolated ß-cells, on isolated islets, or in the whole animal (see Broderick et al., *Biochem. Biophys. Res. Commun.*, 177:932-938 (1991) and references therein).

Amylin or amylin agonists potently inhibit gastric emptying in rats (Young et al., *Diabetologia*, 38(6):642-648 (1995)), dogs (Brown et al., *Diabetes*, 43(Suppl 1):172A (1994)) and humans (Macdonald et al., *Diabetologia*, 38 (Suppl 1):A32 (abstract 118) (1995)). Gastric emptying is reportedly accelerated in amylin-deficient type 1 diabetic BB rats (Young et al., *Diabetologia*, supra; Nowak et al., *J. Lab. Clin. Med.*, 123(1):110-6 (1994)) and in rats treated with the selective amylin antagonist, AC187 (Gedulin et al., *Diabetologia*, 38 (Suppl 1) :A244 (1995)). Methods for reducing gastric motility and slowing gastric emptying comprising the administration of an amylin agonist (including amylin) are the subject of United States Patent Application Serial No. 08/118,381, filed September 7, 1993, and United States Patent Application Serial No. 08/302,069, filed September 7, 1994

(and corresponding PCT application, Publication No. WO 95/07098, published March 16, 1995). The effect of amylin on gastric emptying appears to be physiological (operative at concentrations that normally circulate). Supraphysiological levels of amylin have also been studied with regard to the inhibition of gastric acid secretion (Guidobono, F., et al., Peptides, 15:699-702 [(1995)] (1994) and in regard to protection from gastritis. (Guidobono et al., Brit. J. Pharm., 120:581-86 (1997)). The latter authors reported that subcutaneous injections of amylin had no effect on ethanol- or indomethacin-induced gastritis in rats, although intracerebroventricular injections did have an effect. The same authors also concluded that any gastroprotective effects of amylin were distinct from effects to inhibit acid secretion.—

MARKED UP VERSION OF AMENDED CLAIMS

1. (Three Times Amended) A method for treating or preventing gastritis in a subject in need thereof, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

2. (Three Times Amended) A method for treating or preventing gastric ulceration in a subject in need thereof, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

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4. (Twice Amended) The method of claim [1 or 2] 1, 2, 26, 30, or 31, further comprising administering a non-steroidal anti-inflammatory drug.

4 8 9

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8. (Twice Amended) The method [according to any of claims 1-2] of claim 1, 2, 25, 26, 27, 28, 30, or 31, wherein said amylin agonist is ^{25,28,29}Pro-h-amylin [SEQ. ID. NO. 1].

14. (Once Amended) The method of claim 1 or 2 wherein said IC_{50} of said amylin or amylin agonist is about [50 pM] 5 nM or less in a rat receptor binding assay.

19. (Once Amended) The method of claim [14] 1, 2, 25, or 26, wherein said amylin or amylin agonist has an IC_{50} of about [30 pM] 1 nM or less in a rat receptor binding assay.

CLEAN COPY OF ENTIRE SET OF PENDING CLAIMS

1. A method for treating or preventing gastritis in a subject in need thereof, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

2. A method for treating or preventing gastric ulceration in a subject in need thereof, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

4. The method of claim 1, 2, 26, 30, or 31, further comprising administering a non-steroidal anti-inflammatory drug.

5. The method according to any of claims 1-2, wherein said subject is human.

6. The method according to any of claims 1-2, wherein said amylin or amylin agonist is administered by a route selected from the group consisting of nasal, oral pulmonary, transdermal, and buccal administration.

7. The method according to any of claims 1-2 wherein said amylin agonist is selected from the group consisting of $^{18}Arg^{25,28}Pro$-h-amylin [SEQ. ID. NO. 4], des-$^{1}Lys^{18}Arg^{25,28}Pro$-h-amylin [SEQ. ID. NO. 5], $^{18}Arg^{25-28,29}Pro$-h-amylin [SEQ. ID. NO. 7], des-$^{1}Lys^{18}Arg^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 8], $^{25,28-29}Pro$-h-amylin [SEQ. ID. NO. 1], des-$^{1}Lys^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 9], $^{25}Pro^{26}Val^{28,29}Pro$-h-amylin [SEQ. ID. NO. 6], $^{23}Leu^{25}Pro^{26}Val^{28,29}Pro$-h-amylin [SEQ. ID. NO. 10], $^{23}Leu^{25}Pro^{26}Val^{28}Pro$-h-amylin [SEQ. ID. NO. 11], des-$^{1}Lys^{23}Leu^{25}Pro^{26}Val^{28}Pro$-h-amylin [SEQ. ID. NO. 12], $^{18}Arg^{23}Leu^{25}Pro^{26}Val^{28}Pro$-h-amylin [SEQ. ID. NO. 13], $^{18}Arg^{23}Leu^{25,28,29}Pro$-h-amylin [SEQ.

ID. NO. 14], $^{18}Arg^{23}Leu^{25,28}Pro$-h-amylin [SEQ. ID. NO. 15], $^{17}Ile^{23}Leu^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 16], $^{17}Ile^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 17], des-$^{1}Lys^{17}Ile^{23}Leu^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 18], $^{17}Ile^{18}Arg^{23}Leu$-h-amylin [SEQ. ID. NO. 19], $^{17}Ile^{18}Arg^{23}Leu^{26}Val^{29}Pro$-h-amylin [SEQ. ID. NO. 20], $^{17}Ile^{18}Arg^{23}Leu^{25}Pro^{26}Val^{28,29}Pro$-h-amylin [SEQ. ID. NO. 21], $^{13}Thr^{21}His^{23}Leu^{26}Ala^{28}Leu^{29}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 22], $^{13}Thr^{21}His^{23}Leu^{26}Ala^{29}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 23], des-$^{1}Lys^{13}Thr^{21}His^{23}Leu^{26}Ala^{28}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 24], $^{13}Thr^{18}Arg^{21}His^{23}Leu^{26}Ala^{29}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 25], $^{13}Thr^{18}Arg^{21}His^{23}Leu^{28,29}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 26], and $^{13}Thr^{18}Arg^{21}His^{23}Leu^{25}Pro^{26}Ala^{28,29}Pro^{31}Asp$-h-amylin [SEQ. ID. NO. 27].

8. The method of claim 1, 2, 25, 26, 27, 28, 30, or 31, wherein said amylin agonist is $^{25,28,29}Pro$-h-amylin [SEQ. ID. NO. 1].

9. The method according to any of claims 1 or 2, wherein said gastritis or gastric ulceration is associated with the administration of a non-steroidal anti-inflammatory drug.

10. The method according to claim 4 wherein said non-steroidal anti-inflammatory agent is selected from the group consisting of salicylate, phenylbutazone, indomethacin, acetominophen, phenacetin, naproxen and ibuprofen.

13. The method of claim 1 or 2, wherein said amylin or amylin agonist is amylin.

14. The method of claim 1 or 2 wherein said IC_{50} of said amylin or amylin agonist is about 5 nM or less in a rat receptor binding assay.

15. The method of claim 1 or 2 wherein said gastritis or gastric ulceration is induced by a member selected from the group consisting of ethanol and NSAIDs.

16. The method of claim 15 wherein said member is ethanol.

19. The method of claim 1, 2, 25, or 26, wherein said amylin or amylin agonist has an IC_{50} of about 1 nM or less in a rat receptor binding assay.

20. The method according to claim 6 wherein said route is nasal.

21. The method according to claim 6 wherein said route is oral.

22. The method according to claim 6 wherein said route is pulmonary.

23. The method according to claim 6 wherein said route is transdermal.

24. The method according to claim 6 wherein said route is buccal.

25. A method of treating gastritis or gastric ulceration in a subject in need thereof by peripherally administering an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP, and wherein said amylin or amylin agonist has an IC_{50} of about 5 nM or less in a rat receptor binding assay.

26. A method of treating or preventing gastritis or gastric ulceration, which is induced by ethanol or a non-steroidal anti-inflammatory compound, in a subject in need thereof by peripherally

administering an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP, and wherein said amylin or amylin agonist has an IC_{50} of about 5 nM or less in a rat receptor binding assay.

27. A method for treating or preventing gastritis in a subject, comprising:

peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP; and

administering a non-steroidal anti-inflammatory drug.

28. A method for treating or preventing gastric ulceration in a subject, comprising:

peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP; and

administering a non-steroidal anti-inflammatory drug.

29. A method according to claim 1, 2, 25, or 26, wherein the amylin or the amylin agonist has an IC_{50} value in a rat receptor binding assay of less than about 50 pM.

30. A method for treating gastritis in a subject, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.

31. A method for treating gastric ulceration in a subject, comprising peripherally administering to said subject a therapeutically effective amount of an amylin or an amylin agonist, wherein said amylin agonist is not a calcitonin or a CGRP.